Complete Summary

GUIDELINE TITLE

American Gastroenterological Association medical position statement on treatment of patients with dysphagia caused by benign disorders of the distal esophagus.

BIBLIOGRAPHIC SOURCE(S)

Spechler SJ. American Gastroenterological Association medical position statement on treatment of patients with dysphagia caused by benign disorders of the distal esophagus. Gastroenterology 1999 Jul; 117(1):229-32. PubMed

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Dysphagia caused by benign disorders of the distal esophagus

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Gastroenterology Surgery

INTENDED USERS

Physicians

GUI DELI NE OBJECTI VE(S)

To develop a rational approach to the treatment of adult patients who have dysphagia caused by benign disorders of the distal esophagus

TARGET POPULATION

Adult patients with dysphagia caused by benign disorders of the distal esophagus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Patient history
- 2. Physical examination
- 3. Barium swallow
- 4. Endoscopy
- 5. Esophageal manometry

Management of benign esophageal strictures

- 1. Progressive dilation to 40-60F using mercury-filled bougies, polyvinyl bougies, or balloons
- 2. Proton pump inhibitors
- 3. Antireflux surgery
- 4. Steroid injection
- 5. Self-bougienage

Management of lower esophageal (Schatzki) rings

- 1. Abrupt dilation using a 40-60F mercury bougie, polyvinyl bougie, or balloon
- 2. Pneumatic dilation
- 3. Endoscopic therapy
- 4. Surgery

Management of achalasia

- 1. Pneumatic dilation
- 2. Endoscopy
- 3. Myotomy
- 4. Medical therapy, including, nitrates and calcium channel blockers
- 5. Bougienage using 40-60F dilator
- 6. Botulinum toxin injection
- 7. Feeding gastrostomy

MAJOR OUTCOMES CONSIDERED

- Sensitivity of diagnostic tests
- Stricture patency
- Symptoms of dysphagia
- Lower esophageal sphincter pressure

- Rate of stricture return
- Need for repeat procedures
- Complications of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline considers clinical reports on disease processes that can cause dysphagia that have been published in peer-reviewed journals since 1966. The reports were identified primarily by a MEDLINE search using the following MeSH terms: deglutition disorders, esophageal dysphagia, esophageal stenosis, esophageal motility disorders, and esophageal achalasia. Clinical studies published only in abstract form were not included.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was approved by the Clinical Practice and Practice Economics Committee on September 27, 1998, and by the American Gastroenterological Association Governing Board on November 8, 1998.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

A general approach to the treatment of adult patients who have dysphagia caused by benign disorders of the distal esophagus is outlined in Algorithm 1 of the original guideline document. Historical features strongly suggesting that dysphagia is caused by a disorder of the distal esophagus include the patient's perception that swallowed material sticks at a level below the suprasternal notch and the absence of oropharyngeal symptoms (difficulty in initiation of swallowing, swallowing accompanied by nasopharyngeal regurgitation, pulmonary aspiration, and a sensation that residual material remains in the pharynx).

A barium swallow may be indicated before endoscopy if the clinical suspicion is high for achalasia; it can be difficult to recognize achalasia by endoscopy alone, especially in early cases. If the history, barium swallow, or both suggest achalasia, manometry to confirm the diagnosis usually should precede endoscopic evaluation so that the clinician can be prepared to perform endoscopic therapy for the disorder. A barium swallow also may be warranted before endoscopic examination if the history suggests the possibility of a lesion that might pose a hazard for endoscopy such as a Zenker's diverticulum or a proximal esophageal tumor. If such a lesion is found, the forewarned endoscopist can take appropriate precautions in passing the endoscope.

Reflux esophagitis occasionally causes dysphagia, even in the absence of peptic stricture. After initial endoscopic evaluations that document reflux esophagitis without stenosis, patients whose esophagitis and dysphagia resolve with antireflux therapy require no further tests. Esophageal manometry is recommended for patients whose dysphagia persists despite adequate antireflux therapy (with healing of esophagitis documented endoscopically).

For patients with no lesion demonstrable by barium swallow and endoscopy, limited data suggest that a trial of empiric abrupt dilation (identical to that recommended for treatment of lower esophageal mucosal rings) is safe and reasonably effective. Patients who respond to empiric dilation presumably have subtle rings, webs, or strictures that are missed by diagnostic studies. Esophageal manometry is recommended for patients whose dysphagia persists despite empiric dilation after adequate endoscopic examination has been done.

Peptic Esophageal Strictures

Management of peptic esophageal stricture begins with assessment of whether the stricture is complicated by a small diameter or tortuosity (see Algorithm 2 of the original guideline document). Mercury-filled bougies with diameters less than 10 mm (30F) are so floppy that they tend to curl in the esophagus rather than to traverse complicated strictures. Therefore, guided dilation using polyvinyl bougies or balloons is recommended for tight or tortuous strictures. Simple strictures can be dilated with mercury-filled dilators. The choice among dilator types should be based on the availability of the dilators in a given institution and on the operator's experience and comfort in using them because published experience has not convincingly established the superiority of one dilator type over another.

Esophageal strictures are dilated progressively rather than abruptly. If dilation is performed with bougies, the first bougie passed should have a diameter approximately equal to that estimated for the stricture. Bougies of progressively increasing diameter are introduced until resistance is first encountered, after which no more than two additional bougies are passed during any one session. If balloon dilators are used, the initial dilation usually should be limited to a diameter of no more than 45F. The extent of initial stricture dilation does not seem to influence either stricture recurrence or the requirement for subsequent dilation, so there is little support for the concept that strictures should be dilated aggressively to prevent recurrence. The extent of dilation in an individual patient should be based on the symptomatic response to therapy and on the difficulties encountered during the dilation procedure. Most patients experience good relief of dysphagia with dilation to a diameter between 40F and 54F. Strictures generally should not be dilated to a diameter beyond 60F.

Aggressive antireflux therapy with proton pump inhibitors or fundoplication improves dysphagia and decreases the need for subsequent esophageal dilations in patients with peptic esophageal strictures. For patients whose dysphagia persists or returns after an initial trial of dilation and antireflux therapy, healing of reflux esophagitis should be confirmed endoscopically before dilation is repeated. When healing of reflux esophagitis has been effected, the need for subsequent dilations is determined empirically. For patients whose dysphagia persists or returns quickly despite adequate control of reflux esophagitis, a trial of steroid injection of the stricture can be considered. Patients who experience only short-lived relief of dysphagia after dilation can be taught the technique of self-bougienage. Rarely, truly refractory strictures require esophageal resection and reconstruction.

Lower Esophageal Mucosal Ring

Dilation therapy for lower esophageal mucosal rings involves the passage of a single large bougie or balloon (45-60F) aimed at fracturing (rather than merely stretching) the rings (see Algorithm 3 of the original guideline document). After abrupt dilation, any associated reflux esophagitis is treated aggressively. The need for subsequent dilations is determined empirically. However, recurrence of dysphagia is likely, and patients should be advised that repeated dilation probably will be needed in the future. Esophageal manometry is recommended for patients whose dysphagia persists or returns quickly despite adequate dilation and antireflux therapy. For patients with a treatable motility disorder such as

achalasia, therapy is directed at the motility problem. If no treatable motility disorder is found, endoscopy is repeated to confirm that esophagitis has healed and that the ring has been disrupted. For patients with persistent rings, another trial of abrupt dilation usually is warranted. Refractory rings that do not respond to abrupt dilation using standard balloons and bougies may respond to pneumatic dilation with large balloons (those used to treat achalasia), endoscopic electrosurgical incision, and surgical resection. These therapies should be required only rarely for patients with lower esophageal mucosal rings, and only after other causes of dysphagia have been excluded.

Achalasia

The diagnosis of pseudoachalasia caused by malignancy should be excluded before invasive therapies such as pneumatic dilation or surgical myotomy are implemented. This usually can be accomplished with a careful history and endoscopic examination, although computed tomography and endosonography may be necessary to exclude an infiltrating neoplasm in some cases. Patients with primary achalasia who are good operative risks should be treated with either pneumatic dilation or surgical myotomy (see Algorithm 4 in the original guideline document). Surgery appears to be somewhat superior to pneumatic dilation for both the short-term and long-term relief of dysphagia, and the mortality rates for the two procedures are approximately equal. The major disadvantages for surgery are the high initial cost, the protracted recovery period, and the frequent development of gastroesophageal reflux disease postoperatively. Long-term results are not yet available for myotomy performed using minimally invasive techniques, but the short-term results are promising. Presently, the decision between pneumatic dilation and myotomy as initial therapy for achalasia should be based on a consideration of the patient's preferences, age, and clinical status and on the availability of personnel experienced in the two techniques.

After successful pneumatic dilation, the reappearance of dysphagia suggests either a return of tone in the damaged lower esophageal sphincter muscle or the development of reflux esophagitis with peptic stricture formation. Endoscopic examination usually can differentiate these disorders readily, although manometry occasionally may be required to make this distinction in equivocal cases. Esophagitis is treated with antireflux therapy, and peptic strictures are treated as shown in Algorithm 2 of the original guideline document. If endoscopy shows return of muscle tone in achalasia, the pneumatic dilation is repeated using a larger balloon. Generally, pneumatic dilation should not be repeated more than three times. Patients with persistent or recurrent dysphagia caused by achalasia after three pneumatic dilations should be treated with surgical myotomy.

Patients who represent poor operative risks can be given a trial of medical therapy with nitrates or calcium channel blockers. If these agents are ineffective or poorly tolerated, a trial of abrupt bougienage using a 45-60F dilator can be considered. Botulinum toxin injection of the lower esophageal sphincter can be used for patients whose symptoms do not respond to medical therapy or bougienage. It is also acceptable to use botulinum toxin injection as initial therapy for patients who represent poor surgical risks if the clinician judges that medications and bougienage would be poorly tolerated. Botulinum toxin injection appears to be a safe procedure that can induce a clinical remission for at least 6 months in approximately two thirds of patients with achalasia. However, most patients will

need repeated injections to maintain the remission, and only approximately two thirds of patients in remission at 6 months will remain in remission at 1 year, despite repeated injections. When these treatments have failed, the physician and patient must decide whether the potential benefits of pneumatic dilation or myotomy outweigh the substantial risks that these procedures pose for elderly or infirm patients. A feeding gastrostomy is a safer alternative than pneumatic dilation or myotomy, but many neurologically intact patients find life with a gastrostomy unacceptable.

CLINICAL ALGORITHM(S)

Algorithms are provided for management of dysphagia, management of peptic esophageal stricture, management of lower esophageal mucosal ring, and management of achalasia.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVI DENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. A literature review accompanying the position statement highlights the strengths and weaknesses of the most relevant published studies on patients with dysphagia due to benign esophageal disorders. These studies consist predominantly of retrospective, uncontrolled studies of small heterogeneous patient populations who were followed up only briefly.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of dysphagia caused by benign disorders of the distal esophagus

Subgroups Most Likely to Benefit:

- Patients with achalasia
- Patients with esophageal strictures

POTENTIAL HARMS

Treatment

• The flexibility of the mercury dilators that undoubtedly contributes to their safety becomes a disadvantage in dilation of strictures complicated by tightness, length, and tortuosity. Mercury dilators with diameters of less than 10 mm (30F) are so floppy that they tend to curl in the esophagus rather than to traverse such complicated strictures. Therefore, guided dilation using polyvinyl bougies or balloons may be necessary for stenoses that are exceptionally tight, long, or tortuous.

- The major complications of esophageal dilation are perforation and bleeding. These two complications appear to occur with approximately equal frequency, although there is substantial variation among the reported series. It is difficult to provide precise estimates on the rate of complications for esophageal dilation because of inconsistencies in the available studies. Many reports do not specify precisely the criteria used for the choice of dilation technique, few studies are randomized, and it is difficult to perform a blinded trial of dilation therapy.
- Bacteremia complicates esophageal dilation more than any other procedure performed by gastroenterologists. A number of reports suggest that bacteremia accompanies esophageal dilation in 20%-45% of cases. Despite the high frequency of bacteremia, clinically recognizable infectious complication of esophageal dilation such as endocarditis and brain abscesses have rarely been reported. Although antibiotic prophylaxis for esophageal dilation generally is recommended routinely only for patients at high risk for endocarditis according to the American Heart Association´s guideline, some authorities recently have suggested that such prophylaxis should be given routinely even to patients with "intermediate risk" lesions such as mitral valve prolapse with insufficiency.
- In rare cases, intractable esophageal strictures will require surgical resection and reconstruction. Operative morbidity and mortality are substantially higher for esophageal resection and reconstruction procedures than for antireflux surgery.
- Nitrate therapy for the treatment of achalasia often must be discontinued because many patients experience intolerable side effects (predominantly headache) and because some patients become refractory to the nitrates after an initial good response. Pharmacotherapy for achalasia is inconvenient, often ineffective, and frequently associated with side effects and tachyphylaxis.
- Despite the wide variations in equipment and techniques used for pneumatic dilation for the treatment of achalasia, reported complication rates are remarkably similar. Esophageal perforation is the most common serious complication of the procedure, and most large series describe rates of perforation in the range of 2%-6%. Mortality from pneumatic dilation is rare and has been estimated at approximately 0.2%. The new Rigiflex dilators do not appear to have any safety advantage over the older balloons, and some investigators even suggest that perforation rates are higher with the newer instruments. There are very few reports of studies that have prospectively compared the different dilator types for safety and efficacy, and those that have been published are primarily of historical interest because some of the dilators compared are no longer available.
- Surgical myotomy has a mortality rate of approximately 0.3%. Reflux esophagitis (which may be complicated by esophageal ulceration, stricture, and Barrett's esophagus) has been found to develop in approximately 11% of patients treated by surgical myotomy, and surgeons continue to debate the need for the addition of an antireflux procedure. Late recurrence of dysphagia after surgical myotomy or pneumatic dilation may be caused by a return of tone in the damaged lower esophageal sphincter muscle, by gastroesophageal reflux disease (GERD) with peptic stricture formation, or very rarely by squamous cell carcinoma of the esophagus that develops with increased frequency in patients with achalasia. The major disadvantages for surgery are the high initial cost, protracted recovery period, and frequent development of gastroesophageal reflux disease postoperatively.

Botulinum toxin injection appears to be remarkably safe. Approximately 25% of patients experience transient, mild chest pain immediately after the procedure, and fewer than 5% of patients develop symptomatic gastroesophageal reflux disease (GERD). The most serious complication reported to date is a case report of a patient who developed severe, ulcerative esophagitis (probably caused by acid reflux) after toxin injection. This patient also was found to have adhesions and periesophageal inflammation when he subsequently underwent surgical treatment for achalasia.

Subgroups Most Likely to be Harmed:

- Patients with strictures that are exceptionally tight, long, or tortuous are likely at highest risk for complications from esophageal dilation, although most reports do not supply specific information regarding these stricture variables.
- Physicians should be especially cautious in recommending antireflux surgery for patients with peptic esophageal strictures caused by esophageal motility disorders such as scleroderma. The combination of abnormal esophageal motor function and mechanical obstruction imposed by fundoplication can result in severe postoperative dysphagia.

QUALIFYING STATEMENTS

QUALLEYING STATEMENTS

Even the peer-reviewed literature on the treatment of patients with dysphagia due to benign esophageal disorders consists predominantly of retrospective, uncontrolled studies of small heterogeneous patient populations who were followed up only briefly. The conclusions that can be drawn from these reports often are limited, and the serious deficiencies in study design and execution often preclude meaningful meta-analyses.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

LOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Spechler SJ. American Gastroenterological Association medical position statement on treatment of patients with dysphagia caused by benign disorders of the distal esophagus. Gastroenterology 1999 Jul; 117(1): 229-32. <u>PubMed</u>

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Nov 8 (reviewed 2001)

GUIDELINE DEVELOPER(S)

American Gastroenterological Association - Medical Specialty Society

SOURCE(S) OF FUNDING

American Gastroenterological Association

GUI DELI NE COMMITTEE

American Gastroenterological Association Clinical Practice and Practice Economics Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Association for the Study of Liver Diseases - Private Nonprofit Research Organization

American College of Gastroenterology - Medical Specialty Society American Society for Gastrointestinal Endoscopy - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

According to the guideline developer, the Clinical Practice Committee meets 3 times a year to review all American Gastroenterological Association guidelines. This review includes new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

This guideline has been reviewed by the developer and is still considered to be current as of Dec 2001.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>American Gastroenterological Association</u> (AGA) Gastroenterology journal Web site.

Print copies: Available from American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Spechler SJ. AGA technical review on treatment of patients with dysphagia caused by benign disorders of the distal esophagus. Gastroenterology. 1999 Jul; 117(1): 233-54. [210 references].

Electronic copies: Available from the <u>American Gastroenterological Association</u> (AGA) Gastroenterology journal Web site.

The following is also available:

• The American Gastroenterological Association standards for office-based gastrointestinal endoscopy services. Gastroenterology. 2001 Aug; 121(2): 440-443 [8 references].

Electronic copies: Available from the <u>American Gastroenterological Association</u> (AGA) <u>Gastroenterology journal Web site</u>.

Print copies: Available from American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 5, 2002. The information was verified by the guideline developer on July 12, 2002.

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